K081899

EXHIBIT 2
510(k) Summary

E-Woo Technology Co., Ltd.
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Giheung-Gu, Yongin-Si, Gyeonggi-Do,
Korea 446-904
Tel: 82-31-899-7967
Fax: 82-31-286-3007
Taewoo Kim, President & CEO
AUG 21 2008
January 15, 2008

1. Identification of the Device:
   Proprietary-Trade Name: Portable X-Ray System "AnyRay"
   Classification Name : Unit, X-Ray, Extraoral with Timer / Product Code EHD
   Common/Usual Name: Portable X-Ray System

2. Equivalent legally marketed device:
   This product is similar in design and identical in function to Portable Dental X-Ray System Model "NOMAD" (K051795, Aribex, Inc)

3. Indications for Use (intended use):
   "AnyRay" is Portable X-Ray System intended to be used by trained dentists and technicians as an extraoral x-ray source for producing diagnostic x-ray images using intraoral image receptors. Its use is intended for both adult and pediatric subjects.

4. Description of the device:
   "AnyRay" is a wireless Portable X-Ray System that operates on DC22.5V supplied by a rechargeable Lithum-Polymer battery pack. The X-ray tubehead, X-ray controls and power source are assembled into a single hand-held enclosure. The Package includes DC adaptor and Chair (Option). This equipment generates and controls X-ray in order to diagnose of tooth and jaw. It is composed of x-ray generator, controller, beam limiting device and chair (Option). Operating principle is that x-ray generated by high voltage electricity into x-ray tube, which penetrates tooth and jaw and makes x-ray images on receptor.

5. Safety and Effectiveness, comparison to predicate device

Feature	Predicate: (NOMAD™ Dental X-Ray System, K051795)	New Device Portable X-Ray System "AnyRay"
Manufacturer	Aribex, Inc.	E-Woo Technology Co., Ltd.
Intended Use	Both systems are intended as extraoral x-ray sources to be used with intraoral image receptors for diagnostic imaging by dentists or dental technicians.	
Body Size and Weight	13"L x 11.5H x 5.5"W/ 8.5lbs	8.6"L x 6.0"H x 5.8"W/ 5.3lbs
Chair(Option) and Weight	-	18.8"L x 66.6"H x 27.0"W/76.1lbs
Source to skin distance	20cm	20cm

Cone diameter	6cm	6.5cm
User Interface	Up-down buttons for exposure time selection, with timer display	Up-down buttons for exposure time selection, with timer display
Backscatter radiation protection	6.75" dia. Pb-filled acrylic plastic scatter shield	Circular scatter shield
Exposure switch	On tubehead assembly/control panel	On tubehead assembly/control panel
Tubehead mounting	Handheld	Handheld
Energy Source	Rechargeable 14.4V DC NiCd battery pack	Rechargeable 22.5V DC Lithum-Polymer battery pack.
Exposure Time	0.01 – 0.99 seconds in 0.01 increments	0.06 s ~ 2.0 s seconds in 0.01 increments
Time Accuracy	± (10% + 1ms)	± (10% + 1ms)
mA	2.3mA Fixed	2 mA(Fixed)
kVp	60kVp Fixed	60 kVp(Fixed)
Waveform	Constant Potential(DC)	Constant Potential(DC)
Duty Cycle	1 : 60	1 : 60
Electrical Safety Standards	IEC60601-1, UL60601-1, EN60601-1	IEC60601-1, EN60601-1
EMI Standards	IEC 60601-1-2	IEC 60601-1-2
Performance Standard	21 CFR 1020.30, 1020.31 IEC60601-1-3 IEC60601-2-7	IEC60601-1-3, IEC60601-2-7 IEC60601-2-28, IEC60601-2-32
Biocompatibility	-	Not applicable (No direct, indirect contact with patient)

6. Conclusion

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification E-Woo Technology Co.,Ltd. concludes that the Portable X-Ray System "AnyRay" 's safety and effectiveness are substantially equivalent to predicate devices (NOMAD™ Dental X-Ray System (K051795, Aribex, Inc)) as described herein.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 21 2008

E-Woo Technology Company, Ltd.
% Mr. Tamas Borsai
Responsible Third Party Official
TÜV Rheinland of North America
12 Commerce Road
NEWTOWN CT 06470

Re: K081899
Trade/Device Name: "AnyRay" Portable X-ray System
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: EHD
Dated: August 7, 2008
Received: August 11, 2008

Dear Mr. Borsai:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known) :

Device Name : **Portable X-Ray System "AnyRay"**

Indications For Use : "AnyRay" is Portable X-Ray System intended to be used by trained dentists and technicians as an extraoral x-ray source for producing diagnostic x-ray images using intraoral image receptors. Its use is intended for both adult and pediatric subjects.

Prescription Use __v__ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K081899